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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,193	01/31/2002	Brian Hicke	NEX86/PCT-US	6209

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,193	HICKE ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 44-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 44-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 1 June 2004 in which claims 33 and 50 were amended, a declaration under 37 C.F.R. 1.132 was submitted and the previous rejections were traversed. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 30 January 2004 under 35 U.S.C. 112, first paragraph are maintained. The previous rejections under 35 U.S.C. 102(a) are withdrawn in view of the declaration. All of the arguments have been thoroughly reviewed and are discussed below.

Claims 33 and 44-58 are under prosecution.

Claim Rejections - 35 USC § 112

First paragraph of 35 U.S.C. 112: Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 33 and 44-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for detecting a disease selected from cancer, psoriasis and arteriosclerosis wherein the method comprises detecting the presence of a tenascin-C nucleic acid ligand.

While the specification is enabling for a method of selecting tenascin-C nucleic acid ligands from U251 human glioblastoma cells (Examples 1-2) and for methods for detecting tenascin-C in xenograft tissues in mice using a tenascin-C-specific nucleic acid ligand i.e. TTA 1 (Example 4) wherein the TTA1 ligand detected tenascin-C in three different tumor cell lines glioblastoma, breast, colorectal, and rhabdomyosarcoma (Fig. 6), the specification does not enable one skilled in the art to which it pertains or with which it is most nearly connected to make or use the invention commensurate in scope with the claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to:

Breadth of the Claims

The claims are drawn to a method for detecting a disease selected from cancer, psoriasis and arteriosclerosis wherein the method comprises detecting the presence of a tenascin-C nucleic acid ligand.

The claims are written so broadly so as to encompass any cancerous disease in any tissue or organism using any nucleic acid ligand. The claimed cancers include a wide variety of cancers including any of the large genus of epithelial cancers, hemopoietic, immune system, central nervous system and connective tissue cancers. The broadly drawn method also encompasses detection of cancers in the vary large genus of organisms using a very large genus of nucleic acid ligands.

The specification teaches a method of selecting tenascin-C nucleic acid ligands from U251 human glioblastoma cells (Examples 1-2) and for methods for detecting tenascin-C in xenograft tissues in mice using a tenascin-C-specific nucleic acid ligand i.e. TTA 1 (Example 4) wherein the TTA1 ligand detected tenascin-C in three different tumor cell lines glioblastoma, breast, colorectal, and rhabdomyosarcoma (Fig. 6). However, the specification also teaches that tenascin-C is expressed in a variety of non-diseased tissues e.g. liver, lung, spleen, intestine, kidney (Fig. 7). Because the claims are so broadly drawn to detecting disease by detecting a tenascin-C nucleic acid ligand, because the specification merely teaches detection of a few types of cancer using a single tenascin-C nucleic acid ligand and because the specification teaches tenascin-C expression in non-disease tissue, the specification is not enabling for the broadly claimed invention.

Nature of the Invention

The claims are drawn to a method for detecting a disease selected from cancer, psoriasis and arteriosclerosis wherein the method comprises detecting the presence of a tenascin-C nucleic acid ligand.

The nature of the invention is such that detecting a disease using a ligand would require a teaching of a relationship between the ligand and the disease wherein the teaching would minimally include an illustration or examples of the relationship the ligand and the disease e.g. sample population studies illustrating that tenascin-C expression detects cancer regardless of the amount, time or pattern of expression.

The specification does not provide a teaching such a relationship. The specification teaches that tenascin-C is expressed in three different tumor cell lines glioblastoma, breast,

colorectal, and rhabdomyosarcoma (Fig. 6) but the specification also teaches that tenascin-C is expressed in non-diseased tissues e.g. liver, lung, spleen, intestine, kidney (Fig. 7). The specification does not teach an amount of tenascin-C expression indicative of disease or a temporal pattern of tenascin-C indicative of disease.

While the specification teaches a relationship between tenascin-C and the nucleic acid specific for it, the specification does not teach a relationship between tenascin-C and diseases of cancer, psoriasis and arteriosclerosis which would enable one of skill in the art to make and use the invention as claimed.

Level of Predictability in the Art

The claims are drawn to a method for detecting a disease selected from cancer, psoriasis and arteriosclerosis wherein the method comprises detecting the presence of a tenascin-C nucleic acid ligand.

The level of predictability in the art is very low with regard to detection of disease without a correlating relationship between the disease and the detecting molecule. Because the relationship between tenascin-C expression and cancer, psoriasis or arteriosclerosis is unknown and because tenascin-C is expressed in non-diseased tissue (Fig. 7), the level of predictability that detection of tenascin-C would detect disease is very low. Therefore, the level of predictability in the art is very low with regard to detecting tenascin-C to detect a disease.

Existence of Working Examples

The claims are drawn to a method for detecting a disease selected from cancer, psoriasis and arteriosclerosis wherein the method comprises detecting the presence of a tenascin-C nucleic acid ligand.

The specification teaches a method of selecting tenascin-C nucleic acid ligands from U251 human glioblastoma cells (Examples 1-2); the specification provides working examples of detecting tenascin-C in xenograft tissues in mice using a single tenascin-C-specific nucleic acid ligand i.e. TTA 1 (Example 4); the specification teaches TTA1 detection of tenascin-C in three different tumor cell lines glioblastoma, breast, colorectal, and rhabdomyosarcoma (Example 5 and Fig. 6). However, the specification also teaches that tenascin-C is expressed in a variety of non-diseased tissues e.g. liver, lung, spleen, intestine, kidney (Example 7 and Fig. 7). The specification does not provide working examples of the broadly claimed invention i.e. detection of cancer, psoriasis and arteriosclerosis by detecting a tenascin-C nucleic acid ligand. Therefore, the specification does not provide working examples of the claimed invention which would enable one of ordinary skill in the art to make and use the invention as claimed.

Quantity of Experimentation Required

The claims are drawn to a method for detecting a disease selected from cancer, psoriasis and arteriosclerosis wherein the method comprises detecting the presence of a tenascin-C nucleic acid ligand.

In view of the breadth of the claims being drawn to detecting a large genus of diseases by detecting any of a large genus of tenascin-C nucleic acid ligands; in view of the nature of the invention in which detecting a disease would require a teaching of a relationship between the disease and the ligand being detected and the lack of a teaching in the specification of the

relationship; in view of the of unpredictability in the art with regard to detecting a disease without a correlating relationship between the disease and the detecting molecule; and in view of the lack of working examples of the broadly claimed invention, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

Response to Amendments

Applicant cites the specification (page 1, lines 17-page 2, line 1) as clearly teaches tenascin-C expression in diseased tissues. Applicant asserts that because the prior art, as taught by the specification, recognized that tenascin-C is expressed in a variety of human tumors and hyperproliferative skin disorder and arteriosclerosis, one of skill in the art would recognize a reasonable correlation between the scope of the claims and the enabling disclosure. The argument has been considered but is not found persuasive because, as stated above, the claims are drawn to an enormous genus of diseases including a large genus comprising cancers and further drawn to a large genus of nucleic acid ligands. While the specification teaches a range of disease i.e. during wound healing, neoplasia and is "over-expressed in **many** tumor types including carcinomas of the lung, breast, prostate, and colon, aseocytomas, glioblastokmas. melanomas and sarcomas, the specification does not teach expression of tenascin-C in the enormous genus of disease such that one of skill in the art would be enabled to make and use the claimed invention. It is noted that the specification specifically teaches "many tumor type". While in contrast, the instant claims are drawn to all cancers which the specification does not address or enable one of skill to practice.

Applicant's discussion of Figure 7 is acknowledged. However, the discussion does not alter the fact that the specification does not enable the invention as broadly claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Art Unit: 1634
September 3, 2004